



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,364	07/31/2003	James Wagner	MIY-P01-032	2195
28120	7590	09/15/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			GILBERT, SAMUEL G	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 09/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/631,364

Applicant(s)

WAGNER ET AL.

Examiner

Samuel G. Gilbert

Art Unit

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date see other.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: 12/24/2003, 3/11/2005, 09/06/2005 and 10/21/2005.

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statements filed 12/24/2003, 3/11/2005, 09/06/2005 and 10/21/2005 have been considered. References C1-C75, B63 and B52 have not been considered because no copies have been provided.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim positively recites the sling positioned within the body, thereby positively reciting the human body that is nonstatutory subject matter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7, 9-11 and 13-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gellman et al (6,042,534)

Claims 1 and 3 - element 10- is a sling, an absorbable coating is considered a casing, column 8 lines 3-13.

Claim 2 - the examiner is taking the coating to be considered a sleeve.

Claim 7 - gelatin is taught for the coating, column 8 line 15.

Claim 9 - polyvinyl alcohol is taught in column 8 line 16.

Claim 10 - polyglycolic acid is taught in column 8 line 14.

Claim 11 - polylactic acid is taught in column 8 lines 14 and 15.

Claim 13 - the examiner is taking the coating to be inherently lubricious.

Claim 14 - the sling is capable of being placed as claimed.

Claims 15 and 16 - the claims do not set forth any specific structure to perform the recited functional language therefore the examiner believes the coatings as taught by Gellman et al. will inherently perform as claimed.

Claims 17 and 18 - Gellman et al sets forth a method of providing the sling and casing and positioning it within the periurethral tissues.

Claims 1-3 and 13-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Chu et al (2004/0225181).

Art Unit: 3735

Claims 1 and 2 - element 16 is a sling and element -18- is a bioabsorbable sleeve, paragraphs [0065] and [0075]. The examiner is taking the sleeve -18- as a casing.

Claim 3 - the sleeve -18- is considered a coating.

Claim 13 - the examiner is taking the sleeve -18- to be inherently lubricious.

Claim 14 - the sling is capable of being implanted as claimed.

Claims 15 and 16 - the claims do not set forth any specific structure to perform the recited functional language therefore the examiner believes the coatings as taught by Chu et al. will inherently perform as claimed.

Claims 17 and 18 - Chu et al sets forth a method of providing the sling and casing and positioning it within the periurethral tissues.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gellman et al (6,042,534) in view of Shekalim et al (6,971,813) and Ochoa et al (5,935,172). Gellman et al teaches a device as claimed but does not teach each particular element of the casing as claimed. Gellman et al teaches a coating(casing) to

deliver therapeutic compounds to the body. Shekalim et al teaches a plurality of such therapeutic coatings. Applicant's attention is invited to column 2 lines 7 through column 5 line 31. Ochoa et al teaches polydioxanone among other absorbent material. In the absence of showing any criticality in the exact material selected for the bioabsorbable material the selection of any particular material would have been an obvious design expedient to one of ordinary skill in the medical arts.

Claims 4-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al (2004/0225181) in view of Shekalim et al (6,971,813) and Ochoa et al (5,935,172). Chu et al teaches a device as claimed but does not teach each particular element of the casing as claimed. Coating (casing) is known to deliver therapeutic compounds to the body. Shekalim et al teaches a plurality of such therapeutic coatings. Applicant's attention is invited to column 2 lines 7 through column 5 line 31. Ochoa et al teaches polydioxanone among other absorbent material. In the absence of showing any criticality in the exact material selected for the bioabsorbable material the selection of any particular material would have been an obvious design expedient to one of ordinary skill in the medical arts.

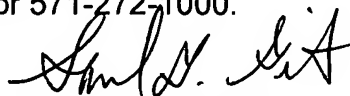
### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 5,352,515 teaches a related mesh structure having a sleeve.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G. Gilbert whose telephone number is 571-272-4725. The examiner can normally be reached on Monday-Friday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Samuel G. Gilbert  
Primary Examiner  
Art Unit 3735

sgg